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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/208,629	12/08/1998	SHAUN R. COUGHLIN	06510/060DIV	8370
25226	7590	11/29/2005	EXAMINER	
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			PAK, MICHAEL D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/208,629

Applicant(s)

COUGHLIN ET AL.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-8, 13-15 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6, 7 and 21-26 is/are allowed.
- 6) ☒ Claim(s) 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

The amendments filed 24 September 2003 has been entered. Claims 1-5, 9-12, and 16-20 have been cancelled. Claims 6-8, 13-15, 21-26 are pending. Claims 13-15 are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed 24 September 2003 have been fully considered but they are not found persuasive.

### ***Specification***

The disclosure is objected to because of the following informalities: The specification on pages 4-5 of the Brief description of drawings does not describe the new figures panels i.e. Figure 1A, 1B, 1C etc.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the disclosed polypeptide comprising the sequence encoding SEQ ID NO:3 or 6, does not reasonably provide the full scope of enablement for a proteinase-activated receptor 3 without a defined structure. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 8 encompasses any protease-activated receptor 3 including those not disclosed in the specification because of the term "analog". However, the specification does not teach how to use any protease-activated receptor including those not disclosed and unknown in the art at the time of the invention because the claims are single means claims. A single means claim is a claim which depend on a recited property, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor (MPEP 2164.08(a)). Thus, as defined by the specification "protease-activated receptor 3" encompasses any cell surface protein which is specifically activated by thrombin or a thrombin agonist (pages 6-7). Thus, the claims encompass any proteins which are activated by protease without the requirement for any structural limitations. It would require undue experimentation to identify and use a receptor where the structure and functional mechanism is not known because the one skilled in the art uses method based on identification by expression cloning or PCR cloning based on sequence identity which requires the knowledge of receptor structure that are different from the G-protein binding receptor family (Nystedt et al.). Specification fails to teach how to make and use receptors which do not belong to the G-protein binding receptor family. Without such disclosure undue experimentation is required to identify and use PAR3 receptors which are different from the PAR3 receptors disclosed in the specification. Therefore, in

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view of the large extent and unpredictable nature of the experimentation which would be involved, one skilled in the art could not make and use the full scope of the invention as claimed without undue experimentation.

Applicants argue that a sequence identifier has been provided for claim 8.

However, the term "analog" encompasses a large scope PAR3 receptors which are not enabled as discussed above.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 8 encompasses protease activated receptor peptide variants and fragments which encompasses a large genus of G-protein receptor. However, the essential feature of the invention is the peptide of SEQ ID NO:3 and 6, and one of skilled in the art cannot envision the full genus of antibodies which bind claimed variant molecules. The claims encompass receptors whose structure is not known or other variant proteins with different function from SEQ ID NO:3 and 6 taught in the specification because the term "comprising" and "analog" encompass structures which is not part of SEQ ID NO:3 and 6. Claimed receptor encompass a large genus of proteins which which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally

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occurring protein is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

***Claim Rejections - 35 USC § 102***

Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Coleman et al. (US 5,686,597).

Coleman et al. disclose a thrombin receptor homolog (TRH; column 3, lines 50-67).

Although TRH is not called a protease activated receptor 3, TRH is encompassed within the family of protease activated receptors because thrombin receptors are protease activated receptors (column 1, lines 10-25) and is not excluded by the definition of "protease activated receptor 3" in the specification on pages 6-7. Claim 8 recite "analog" which encompasses variants of protease activated receptor 3 and is met by the TRH of Coleman et al.

Claims 6-7 and 21-26 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-

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7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0839.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Michael D. Pak*

Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
22 September 2005